REMARKS

This is in response to the Office Action mailed October 13, 2009. Claims 1, 5, 7-10, 14, 15, 17 and 18-20 are pending in the application. Claims 1 and 10 have been amended. Claims 18-20 have been withdrawn and claims 2-4, 6, 11-13, 16 and 21-26 have been canceled. Applicant respectfully requests reconsideration of the application based on the following remarks.

SPECIFICATION

The disclosure has been objected to because the specification contains sequences on Page 4 which are not identified by SEQ ID Nos. and do not appear to be included in the sequence listing. Applicants have amended page 4 to insert the SEQ ID Nos. of the sequences recited therein.

I. CLAIM REJECTIONS UNDER 35 U.S.C. §101

Claims 1-13 and 21-25 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. It is the Examiner's position that claims 1-13 and 21-25, as written, do not sufficiently distinguish over peptides as they exist naturally because the claims to not particularly point out any non-naturally occurring differences between the claimed peptides and the structure of naturally occurring peptides.

Applicants respectfully traverse the rejection for at least the following reasons. Claim 1 has been amended to recite a peptide having the general structural formula: His-Gly-Val-Ser-Gly-Trp-Gly-Gln-His-Gly-Thr-His-Gly. The peptide of SEQ ID No. 1 (allostatin-1) of the claimed invention is an artificial sequence, as it is mentioned in the List of Sequences, and is significantly different from the structure of any known natural or synthetic peptides represented in Swissprot or other available protein and peptide data bases. It was obtained by the chemical synthesis process described on pages 3 and 6 of the specification.

Furthermore, the biological activity of the peptide SEQ ID NO. 1 (allostatin-1) differs from the activity of structurally similar naturally occurring peptide alloferon 1 (SEQ ID No. 12) in the way that makes allostatin-1 more prospective for clinical as is

demonstrated in the Example 2 of the specification. Thus the peptide SEQ ID NO. 1 (allostatin-1), being a non-natural, new and useful entity, meets the requirements of 35 U.S.C. §101.

II. CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 1-2, 6-17 and 22-26 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fishleigh et al. (U.S. Patent No 5,773,572). The Examiner contends that Fishleigh et al. discloses structures of polypeptides of SEQ ID Nos. 30, 31 and 46 corresponding to the formula X_1Trp Gly Gln X_2 discloses in the present application.

Applicants respectfully traverse the rejection for at least the following reasons. Claim 1 has been amended to recite a peptide having the general structural formula: His-Gly-Val-Ser-Gly-Trp-Gly-Gln-His-Gly-Thr-His-Gly. The peptide of SEQ ID No. 1 on the whole has very limited homology with the polypeptides of SEQ ID Nos. 30, 31 and 46 as disclosed in Fishleigh et al. Table 1 below clearly illustrates that only 5 or 13 aminoacids (38%) constituting SEQ ID No. 1 currently claimed coincide with the sequences of Fishleigh et al.

Table 1

SEQ ID NO 1 Allostatin 1 Current Application	His	Gly	Val	Ser	Gly	Trp	Gly	Gln	His	Gly	Thr	His	Gly
SEQ ID NO 30 f. 1-12 Fishleigh et al.	Xaaa		Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly
SEQ ID NO 31 f. 1-12 Fishleigh et al.	Xaaa		Gly	Gly	Gly	Trp	Gly	Gln	Gly	Gly	Gly	Thr	His
SEQ ID NO 46 f. 3-15 Fishleigh et al.	Pro	His	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly

Moreover, the most significant differences are functionally important, namely:

(1) His (Polar positively charged amino acid) in the positions 1, 9 and 12 of SEQ ID No. 1 is replaced by Pro (nonpolar amino acid) in the Fishleigh et al. sequences;

(2) Gly in the positions 2, 10 or 13 of SEQ ID No. 1 is replaced by His in the corresponding positions in the Fishleigh et al. sequences; and

(3) Thr (polar noncharged amino acid) in the position 11 of SEQ ID No. 1 is replaced by Gly in the Fishleigh et al. sequences.

Such nonconservative replacements inevitably change the properties of the peptide molecule as a whole.

While the antiproliferative, antitumoral, antiviral and immunomodulatory activities are considered inherent properties of the particular polypeptide sequence, the *differences* in the sequences certainly create differences in the biological activities. Fishleigh et al. does not teach or suggest in any manner that the peptides of SEQ ID Nos. 30, 31 and 46 or other parts of prion proteins or whole prions may have activities possessed by the peptide of SEQ ID No. 1 of the present invention, namely antiproliferative, antitumoral, antiviral and immunomodulatory activities. Furthermore, Fishleigh et al. teaches that the peptides of SEQ ID Nos. 30, 31 and 46 can be used as antigens for anti-prion antibodies development, a property that is quite different from the activities of the peptide of SEQ ID No. 1 of the present invention.

In view of the amendment to claim 1 and the foregoing remarks, Applicants respectfully submit that the subject matter of claims 1, 7-10, 14, 15 and 17 in neither anticipated by, nor rendered obvious by Fishleigh et al.

III. PRIOR ART MADE OF RECORD AND NOT RELIED UPON

The Examiner has cited US Patent Publication 2003/0166558 (Frangione et al.) as being considered pertinent to applicant's disclosure.

Applicants wish to submit the following comments with regard to Frangione et al. The term "immunomodulatory activity" in the context of the current application applies to two quite different kinds of immunotropic activities. Frangione et al. teaches that the peptides can be used "for inducing an immune response to amyloid β peptides and amyloid deposits, to prion protein and prion deposits, to amylin and amylin deposits, to α-synuclein and deposits containing α-synuclein…". Frangione et al. does not teach any other immunogenic activities of the peptides except their antigenic properties. According to Frangione et al., the peptides of their invention can be useful for the treatment or prevention of neurodegenerative disorders caused by amyloid proteins or

prions aggregation. There are no indications or suggestions to use said peptides for viral infections or tumors treatment.

On the contrary, the peptide of the present invention, SEQ ID No. 1 (allostatin-1), possesses immunomodulating activity mediated by induction of interferon synthesis in blood leukocytes. Inteferons, when activated, may in their turn activate antiviral cellular defenses and modulate other chains of antiviral and antitumoral immunity. According to the application, the peptide can be useful for the treatment of viral infections and tumors. Thus, there is no overlapping or causal relationship between the immunogenic (antigenic) properties of Frangione et al. peptides and the immunomodulatory (interferonogenic) activity of peptide SEQ ID No. 1 (allostatin-1). Moreover, Applicants wish to point out that the 13 amino acid sequence constituting SEQ ID No. 1 has poor similarity compared to the corresponding prion protein 13 amino acid sequences comprising the Trp-Gly-Gln triplet of Frangione et al. (see Table 2 in the attached Appendix) and has no any similarity with any other motifs of prion proteins, amyloid β, amylin or α-synuclein. Furthermore, SEQ ID No. 1 (allostatin 1) peptide appears to be too small (molecular mass 1316 dalton) to have any antigenic activity. Therefore, the peptide SEQ ID No. 1 (allostatin 1) immunomodulatory (intereferonogenic) activity cannot be attributed to the immunogenic (antigenic) activity disclosed by Frangione et al.

In summary, the structure, biological properties and prospective use of the peptide SEQ ID No. 1 of the present invention differs from the peptides disclosed by Frangione et al.

Conclusion

Accordingly, claims 1, 5, 7-10, 14, 15, 17 are believed to be allowable and the application is believed to be in condition for allowance. A prompt action to such end is earnestly solicited.

Should the Examiner feel that a telephone interview would be helpful to facilitate favorable prosecution of the above-identified application, the Examiner is invited to contact the undersigned at the telephone number provided below.

Should a petition for an extension of time be necessary for the timely reply to the outstanding Office Action (or if such a petition has been made and an additional extension is necessary), petition is hereby made and the Commissioner is authorized to charge any fees (including additional claim fees) to Deposit Account No. 18-0988 (Docket No: **SPSUP0100WOUS**).

Respectfully submitted,

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Appendix

Table 2

Sequence comparison of the peptide SEQ ID NO 1 (Allostatin 1) and Trp-Gly-Gln comprising fragments of prion proteins cited in Frangione et al.

SEQ ID NO 1 Allostatin 1 Current Application	His	Gly	Val	Se	Gly	Trp	Gly	Gl	His	Gly	Thr	His	Gly	Homo-logy, %
SEQ ID No 21 f 52-64 Frangione et al	Gly	Gly	Gly	Gly	Gly	Trp	Gly	Gl	Pr	His	Gly	Gly	Gly	46
SEQ ID No 21 f f 61-80, 68-80, 76-88 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gl	Pr	His	Gly	Gly	Gly	38
SEQ ID No 21 f 84-96 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gl	Gly	Gly	Gly	Thr	His	38
SEQ ID No 22 f 52-64 Frangione et al	Pro	Gly	Gly	Gly	Gly	Trp	Gly	Gl	Pr	His	Gly	Gly	Gly	46
SEQ ID No 22 f f 60-72, 68-80, 76-88 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gl	Pr	His	Gly	Gly	Gly	38
SEQ ID No 22 f f 84-96 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gl	Gly	Gly	Gly	Thr	His	38
SEQ ID No 23 f f 52-64 Frangione et al	Pro	Pr	Gly	Gly	Gly	Trp	Gly	Gl	Pr	His	Gly	Gly	Gly	38
SEQ ID No 23 f f 60-72, 68-80, 76-88 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gl	Pr	His	Gly	Gly	Gly	38
SEQ ID No 23 f f 84-96 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gl	Gly	Gly	Gly	Thr	His	38
SEQ ID No 24 f 51-63 Frangione et al	Pro	Gl	Gly	Gly	Thr	Trp	Gly	Gl	Pr	His	Gly	Gly	Gly	31
SEQ ID No 24 f 59-71 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gl	Pr	His	Gly	Gly	Ser	31
SEQ ID No 24 f 67-79 Frangione et al	Pro	His	Gly	Gly	Se	Trp	Gly	Gl	Pr	Pr	Gly	Gly	Ser	23
SEQ ID No 24 f 75-87 Frangione et al	Pro	Pro	Gly	Gly	Ser	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	31

SEQ ID No 24 f 85-95 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gln	Gly	Gly	Gly	Thr	His	38
SEQ ID No 25 f 24- 36 Frangione et al	Gln	Ser	Gly	Gly	Thr	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	31
SEQ ID No 25 f 32- 44 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	38
SEQ ID No 25 f 40-52, 48-60 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	38
SEQ ID No 26 f 52-64 Frangione et al	Pro	Pro	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	38
SEQ ID No 26 f 60-72, 68-80, 76-88 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	38
SEQ ID No 26 f 84-96 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gln	Gly	Gly	Gly	Thr	His	38
SEQ ID No 27 f 55-67 Frangione et al	Gln	Gly	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	46
SEQ ID No 27 f f 63-75, 71-83, 79-91 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	38
SEQ ID No 27 f 88-100 Frangione et al	His	Gly	Gly	Gly	Gly	Trp	Gly	Gln	Gly	Gly	Gly	Ser	His	54
SEQ ID No 28 f 55-67 Frangione et al	Pro	Pro	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	38
SEQ ID No 28 f 63-75, 71-83, 79-91 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	38
SEQ ID No 28 f 88-100 Frangione et al	His	Gly	Gly	Gly	Gly	Trp	Gly	Gln	Gly	Gly	Ser	His	Ser	54
SEQ ID No 29 f 55-67 Frangione et al	Gln	Gly	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	46
SEQ ID No 29 f 63-75, 71-83, 79-91 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	38
SEQ ID No 29 f 88-100 Frangione et al	His	Gly	Gly	Gly	Gly	Trp	Gly	Gln	Gly	Gly	Ser	His	Ser	54
SEQ ID No 30 f 55-67 Frangione et al	Gln	Gly	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	46

SEQ ID No 30 f 63-75, 71-83, 79-91, 87-99 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	38
SEQ ID No 30 f 96-108 Frangione et al	His	Gly	Gly	Gly	Gly	Trp	Gly	Gln	Gly	Gly	Thr	His	Gly	69
SEQ ID No 31 f 55-67 Frangione et al	Gln	Gly	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	46
SEQ ID No 31 f 63-75, 71-83, 79-91, 87-99 Frangione et al	Pro	His	Gly	Gly	Gly	Trp	Gly	Gln	Pro	His	Gly	Gly	Gly	38